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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/27/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,205

Applicant(s)

DURING, KLAUS

Examiner

Juliet Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to processes for the production of a fibrous protein, plant cells, and transgenic plants.

Group II, claim(s) 18-19, drawn to collagen proteins.

Group III, claim(s) 18 and 20, drawn to elastin proteins.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

There is no special technical feature which joins the claims because the broadest claims of the first claimed invention are anticipated in the prior art (see 102 rejections over Daniell *et al.* and/or Kivirikki *et al.*) PCT Rule 13.2 states “The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes *over the prior art*. (emphasis added)” Since the method of claim 1 is anticipated, this invention provides no special technical feature over the prior art.

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3. During a telephone conversation with Birgit Millauer on 7/16/01 a provisional election was made with traverse to prosecute the invention of group I, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

4. The substitute specification filed 3 January 2001 has not been entered because it does not conform to 37 CFR 1.125(c) because the paragraphs of the substitute specification are not numbered individually in Arabic numbers so that any amendment to the specification may be made by replacement paragraph.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-10, 12, 14, 15, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 and 17 are indefinite because there is not a clear connection between the preamble of the claims and the method steps, and thus it is not clear how the preamble of the claims breaths life into the method. For example, claim 1 recites "a process for the production of a fibrous protein," and then finishes with a final process step of incubating a precursor fibrous protein with a protein processing it. The method steps do not set forth or require that the incubating step result in the processing of the precursor fibrous protein into a fibrous protein,

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merely that the precursor protein be incubated with a processing protein. Thus, it is unclear if the claims are intended to be directed towards the production of fibrous proteins or towards the incubation of precursor proteins. Amendment of the method steps to require that the incubating results in the formation or production of a fibrous protein would obviate this rejection.

Claims 6-9 are indefinite over the language “or a derivative and fragment thereof” because this language is vague and indefinite. It is not clear if the “and” means to imply that all derivatives are also fragments of the named proteins. Furthermore, it is not clear how much of a fragment thereof is required to be present for the protein of interest to be considered a procollagen, tropoelastin, collagen, or elastin, respectively. Clarification of the claims is required.

Claims 10, 14, 15 and 16 are indefinite over the recitation of “a protein processing precursor fibrous protein” because it is confusing what is intended by this language. Amendment of the claims to read a protein which processes a precursor fibrous protein would overcome this rejection.

Claims 12 and 15 are indefinite over the recitation “said plant cell is part of a multiplication material” because it is not clear what is meant by being part of a multiplication material, and the specification does not provide a definition for this phrase. For example, it is not clear if this phrase means that the cells are part of a cell culture or if it means that the cells are part of a plant with cells that are dividing (multiplying) or if being part of a “multiplication material” has some other meaning all together. Clarification is required.

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7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1, 2, 3, 4, 6, 8, 10, 11, 12, 14, 15, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kivirikki *et al.* (WO 97/38710).

Kivirikki *et al.* teach a process for the production of a fibrous protein comprising (a) expressing a precursor fibrous protein in a plant cell (p. 10, lines 5-9); and (b) incubating the precursor fibrous protein with a protein processing it (p. 8, lines 13-16; p. 9, lines 18-20). Kivirikki *et al.* teach that the processing protein can be lysine oxidase (p. 19, lines 14-26), and further teach methods in which lysine oxidase is expressed in the same host cell as the precursor protein (p. 8, lines 13-16) or in a different host cell (examples 1 and 7). Kivirikki *et al.* teach the expression of precursor protein that is procollagen, thus the fibrous protein produced is a collagen. Kivirikki *et al.* thus provide plant cells expressing a precursor fibrous protein as well as plant cells expressing a protein which processes a precursor fibrous protein. Further, Kivirikki

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et al. provide cells which are available on a multiplication media, since all of the cells taught by Kivirikki *et al.* are in grown in cultures.

9. Claims 1, 5, 7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniell *et al.* (US 6004782).

Daniell *et al.* teach methods for the production of a fibrous protein comprising expressing a precursor fibrous protein in a plant cell ; and incubating the precursor fibrous protein with a protein processing it (Col. 15, lines 55-65). Daniell *et al.* teach methods wherein the cell is part of a plant. The precursor molecules taught by Daniell *et al.* include (GVGVP)₁₂₀ and G-(VPGVG)₁₉-VPGV which are tropoelastins or a derivative and a fragment thereof (Col. 19, Example 4 and Col. 20, Example 20), and the fibrous protein being produced is therefore an elastin.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kivirikki *et al.* (WO 97/38710) in view of Zhang *et al.* (Plant Cell Reports (1996) 16:174-179).

Kivirikki *et al.* teach a process for the production of a fibrous protein comprising (a) expressing a precursor fibrous protein in a plant cell (p. 10, lines 5-9); and (b) incubating the precursor fibrous protein with a protein processing it (p. 8, lines 13-16; p. 9, lines 18-20).

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Kivirikki *et al.* teach that the processing protein can be lysine oxidase (p. 19, lines 14-26), and further teach methods in which lysine oxidase is expressed in the same host cell as the precursor protein (p. 8, lines 13-16) or in a different host cell (examples 1 and 7). Kivirikki *et al.* teach the expression of precursor protein that is procollagen, thus the fibrous protein produced is a collagen. Kivirikki *et al.* thus provide plant cells expressing a precursor fibrous protein as well as plant cells expressing a protein which processes a precursor fibrous protein. Further, Kivirikki *et al.* provide cells which are available on a multiplication media, since all of the cells taught by Kivirikki *et al.* are grown in cultures.

Kivirikki *et al.* do not teach methods in which the cells are available in a transgenic plant, nor do they teach methods in which the precursor protein is a tropoelastin.

Zhang *et al.* teach methods for the production of production of a fibrous protein which comprise (a) expressing a precursor fibrous protein in a plant cell, wherein the plant cell is available as part of a plant and therefore as part of a multiplication material since the cells of the plants are constantly dividing (p. 175). Zhang *et al.* are producing tropoelastin polymers or fragments or derivatives thereof (p. 175-175).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the methods taught by Kivirikki *et al.* with those taught by Zhang *et al.* to have arrived at methods for producing transgenic plants that express fibrous precursor proteins. The ordinary practitioner would have been motivated by Zhang *et al.*'s teaching that it is advantageous to produce such proteins in plants because it is expensive to produce precursor proteins by routine fermentation methods, and a strategy for reducing production cost "would be to produce polymers in plants, because plants are cheap to grow on a

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large scale.” Furthermore, It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have incubated the tropoelastins produced in the methods taught by Zhang *et al.* with the processing proteins taught by Kivirikki *et al.* in order to achieve the goal of producing cross-linked polymers for the commercial utilities taught by Zhang *et al.* (p. 174). Thus, given the combined teachings of Kivirikki *et al.* in view of Zhang *et al.* the instantly claimed invention is *prima facie* obvious in view of the prior art.


Conclusion


12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600


Juliet C. Einsmann
Examiner
Art Unit 1634

March 21, 2002